Labeling Recommendations for Single Use Devices Reprocessed by Hospitals

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Device Labeling Recommendations for Single Use Devices Reprocessed by Third Parties and Hospitals (www.fda.gov/cdrh/comp/guidance/1392.pdf)

- This guidance applies to hospitals and third parties that reprocess SUDs.

FDA Labeling Rules (Part 801 of the Act)

- All devices, including reprocessed SUDs, need to meet the labeling rules of the Act. If not properly labeled, they are misbranded.

General Labeling Rules

- Applies to persons who manufacture, use, ship, or sell reprocessed SUDs.

General Labeling Rules

- name and location of
  - manufacturer,
  - packer, or
  - distributor
  - (section 502(b) of the Act ; 21 CFR 801.1)

General Labeling Rules

- common or usual name of SUD (section 502(e)(2) of the Act)
- quantity of items in the package (section 502(b)(2) of the Act)
- directions on how to use device (section 502(f)(1) or 21 CFR 801.109)

General Labeling Rules

- all necessary warnings (section 502(f)(2) of the Act)
- only truthful statements (section 502(a) of the Act)

Manufacturer's Name

- If a hospital reprocesses a SUD, it is making a new device from a used SUD and its name and address should appear on the label of the new device.
  (21 CFR 803.3(o); 806.2(g); 807.3(d); 820.3(o); 821.3(c))

Directions on How to Use

- Directions for use by a layperson are required for non-prescription devices (21 CFR 801.5)
- Directions for use by a licensed practitioner (physician are required for prescription devices (21 CFR 801.109)

Labeling Prescription Reprocessed SUDs

- Must have on the label, at least:
  - the statement “Caution: Federal law restricts this device to sale by or on the order of (e.g., a physician,); and
  - how the reprocessed SUD should be applied or used.

Labeling Prescription Reprocessed SUDs

- Must have:
  - information for use, including directions, indications, methods, frequency and duration, and contraindications, warnings precautions, etc.
  - Unless this information is commonly known to practitioners licensed to use the device.

Labeling Non-Prescription Reprocessed SUDs

- An OTC reprocessed SUD must follow the rules about the main display panel, what it is, and how many are in a package. (21 CFR 801.60)

Use of Previous Manufacturer's Labeling

- Put hospital name and location on the label (21 CFR 801.1); and
- Statements in the previous manufacturer’s labeling may be false or misleading, and the directions for use may no longer be applicable.
- Copyright or trademark issues

Third Party Reprocessor

- If a hospital uses a 3rd party SUD reprocessor, put on the labels of the used SUDs: “Caution: For manufacturing, processing, or re-packing.” (21 CFR 801.122)
- The 3rd party SUD reprocessor must provide directions for use. (21 CFR 801)

Additional Information

- **Reuse web site at:**
  http://www.fda.gov/cdrh/reuse/index.shtml